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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/592,695	06/13/2000	Andrea G Cochran	P1762R1	7146

7590

08/28/2002

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EXAMINER

WESSENDORF, TERESA D

ART UNIT	PAPER NUMBER
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1627

DATE MAILED: 08/28/2002

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/592,695

Applicant(s)

COCHRAN ET AL.

Examin r

T. D. Wessendorf

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 4 and 15-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-3 and 5-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-5, species, TW(EGNK)WT [A1-A5] in Paper No. 13 is acknowledged. Note that at page 2, of the election, applicants elected T for A1. It is assumed that this is for A5 since T has already been elected for A1.

Claims 4 and 15-18 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13. Claim 15 is similarly withdrawn from consideration since it is drawn to a different compound i.e., a fusion cyclic peptide. Claim 1 simply reads a cyclic library of peptide.

Accordingly, the claims pending in the instant invention are claims 1-3, 5-14.

Specification

The attempt to incorporate subject matter into this application by reference to U.S. Patent Serial Nos. 60/103,514 and 60/134,780 is improper because these pending applications disclose a plasmid for producing the claimed library.

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The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

The disclosure is objected to because of the following informalities: the status of the applications recited at page 35, line 6 and line 19 has not been provided.

Appropriate correction is required.

The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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Drawings

The drawings are objected to because of the reasons set forth at PTO 948. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Priority

The first sentence of the specification following the title, claims priority to the provisional application S.N. 60/139,017 filed June 14, 2000. The filing date is inconsistent with the Oath filing date of 6/14/99. (See also, the non-provisional application under 37 CFR 1.53(b) which claims the same filing date as that in the oath).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3 and 5-14 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter and lacks patentable utility.

The claimed library of structurally constrained peptides comprising a plurality of cyclic peptide of the recited formula is a non-statutory subject matter since it reads on naturally occurring peptides. This is evident from applicants' statement in the instant disclosure, page 1, lines 11-14. Applicants state that "...in their natural environment, peptides ...adopt unique, conformationally-constrained structures in order to recognize and bind to their binding partners....."

Accordingly, the library of the instant invention which is but a mixture of the cyclic peptides is but the same mixture found in nature. A mixture of compounds already found in nature is not considered a new product. Furthermore, the claimed mixture (i.e., library as claimed) does not have any utility except, as alleged, to screen for new and useful products. All naturally occurring compositions even the synthetically made ones are screened to ultimately obtain a new and useful single product. Screening of a library, in by itself, cannot be construed as a use for the library, since the ultimate intended single product is evidently the one that is useful within the requirement of the law. There can be no specific use for a complex mixtures of a composition comprised of different components that could exhibit all kinds of reactions and all kinds of products. Thus, since all compositions or mixtures

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(library, as claimed), whether naturally or non-naturally occurring (synthetic products) is subjected to screening since a library is not a unitary component but rather, a mixture of complex components.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-14 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification fails to provide an adequate written description for the instantly claimed library. There is nothing in the disclosure that discloses what the library of the peptide is useful for. The specification, specifically the Examples, given by applicants as illustrative of the claimed invention, merely provides studies or investigates whether the disulfide-constrained peptide sequence can form a scaffold for beta-turn

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display. Example 6 of the disclosure relates to further studies in screening the library for a clone. It is apparent from the disclosure that this appears to be the only written description as to the use for the peptide library. There is no other description as to the use of the library except, as stated, to screen the disulfide constraining peptide library. However, screening of a library, in by itself, cannot be construed as a use for the library, since the ultimate intended single product is evidently the one that is useful within the requirement of the law. There can be no specific use for a complex mixtures of a composition comprised of different components that could exhibit all kinds of reactions and all kinds of products. Thus, all mixtures (library, as claimed), whether naturally or non-naturally occurring (synthetic products) undergoes screening since the libraries are not a unitary component but rather, a mixture of complex components. Therefore, screening a composition comprised of numerous components is not considered an adequate description of use for the peptide library. These investigational studies do not correspond to the written description requirement, as it is not readily apparent from these studies the specific use of the peptide library.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 5-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A). Claim 1 is unclear as to the optional protection of C1 at the carboxy group. Is a non-amide bond formed between the first C1 residue and Thr at position A1? This rejection applies equally to C2 optional protection at the amino terminus.

b). The elected species is not positively recited in the specification.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the claimed elected species lacks antecedent support in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another

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who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4, 5, 8 and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Wrighton et al [5,830,851(I)] or Wrighton et al [Science(II)].

Wrighton et al discloses at col. 5, lines 9-10 and col. 6, line 47 a library of peptide based on the sequence GGYSSCHFGPLTWCKPQGG (Seq. ID. 8). Accordingly, the specific peptide library of Wrighton fully meets the claimed library of peptide having any of the various definitions for the A1-A5 variables comprised in the peptide sequence. [Note that the structure of the other residues comprising Seq. ID. No. 1 is not completely recited therein].

Wrighton discloses at page 458, abstract a 14 amino acid disulfide-bonded cyclic peptide with a minimum consensus sequence YXCXXGPXTWXCXP where X is a residue position allowing

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occupation by several amino acids. Wrighton discloses a specific peptide at page 459, Table 1, specifically the peptide EMP4. The broad claimed peptide library comprising of the claimed peptide sequence is anticipated by the peptide of Wrighton drawn to a specific peptide of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4, 5, 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wrighton et al or Wrighton et al.

Each of these references is discussed, above. Each of these references discloses a library of peptide sequence with amino acid residues attached before and after the disulfide residues. The claimed library of peptide comprising of the claimed peptide sequence is an open-ended language and can contain any amino acid residues of unspecified length. Accordingly, Wrighton (I or II) would render the claimed peptide library prima facie obvious

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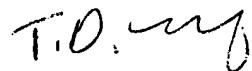
since the prior art peptide library sequence is encompassed by the broad claimed peptide library sequence comprising the core sequence Seq. ID.I.

The elected species is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is (703) 308-3967. The examiner can normally be reached on Flexitime.

The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7924 for regular communications and (703) 308-7924 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


T. D. Wessendorf
Primary Examiner
Art Unit 1627

tdw
August 23, 2002